PDBP
Parkinson's Disease Biomarkers Program

Protocol Deviations

* **Required fields**

*Name of Site: _____

*Type of Visit: _____
e.g. Screening, Baseline, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 42 months, 48 months, 54 months, 60 months.

*Date of Visit: _____

*GUID: _____

*Age of Subject (years and months): _____

Subject ID: _____

Were there any deviations from the protocol that occurred during the care of this participant/subject, after enrollment and before participant/subject exited the study?

☐ **Yes** (Record exceptions below) ☐ **No** (Stop)

Description of Protocol Deviation	Date Deviation Occurred (mm/dd/yyyy)
	__ __/__ __/20__ __
	__ __/__ __/20__ __
	__ __/__ __/20__ __
	__ __/__ __/20__ __
	__ __/__ __/20__ __

Protocol Deviations CRF Module Instructions

General Instructions

INTRODUCTION

A protocol deviation is a failure to conduct all aspects of the study as described in the protocol. The term, “protocol violation” comes from CFR 312.64 which states that, “No changes to research are made without IRB approval except when necessary to eliminate hazards to human subjects.” The Food and Drug Administration (FDA) may identify a violation of the Act and thus use the term “protocol violation.” Because of the legal implications of “protocol violation”, the term “protocol deviation” is more appropriate for investigators, coordinating centers, and other study staff.

PROTOCOL DEVIATIONS CONTINUUM

Protocol deviations encompass a continuum of departures from an approved study protocol from minor to major or critical, major, minor; or critical, urgent, significant.

It is frequently argued that the term “minor” implies something that can be readily addressed, without significant consequence to the study participant/subject or data quality and thus should not be considered a protocol deviation. An example of a minor deviation would be a visit occurring outside the window defined in the protocol (e.g., + 3 days) because of weather or vacation. The protocol drives the importance of a protocol deviation. The study staff should define protocol deviations that should be documented in the Deviation Log.

A major or critical protocol deviation is one that may impact participant/subject safety, affect the integrity of study data and/or affect participant/subject’s willingness to remain in the study. An example of a major violation is an unreported serious adverse event (SAE) or use of a prohibited medication. Examples of major deviations include:

- Failure to obtain/maintain approval for research,
- Failure to obtain informed consent when required,
- Failure to file adverse event reports,
- Use of a prohibited drug
- Performance of research at an unapproved site,
- Failure to file protocol modifications and failure to adhere to an approved protocol.

IDENTIFICATION OF DEVIATIONS

Protocol deviations described in the protocol and/or MOP should be recorded on the Protocol Deviation Log when identified by the Principal Investigator or site staff. Data coordinating centers are also likely to discover deviations during the quality checking of the study data and should notify the site of identified deviations. Likewise, deviations may also be discovered during visits from a monitor or auditors and they will inform the site of their discovery.

Protocol deviations are summarized for Data Safety Monitoring Boards (DSMBs) and an investigator may be required to report critical or major deviations to the Institutional Review Board (IRB).

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- **Any Deviations?** – Choose one. If this question is answered YES then at least one protocol deviation should be recorded.
- **Description of Protocol Deviation** – Record what occurred and why. For example, an expired drug was used by a new coordinator who did not check the expiration date because of incomplete training on the protocol. The description should also include remedies taken. In this case, the participant/subject was called to return the drug and was issued unexpired medication. Further, the coordinator received complete training and was certified on the protocol.
- **Date Deviation Occurred** – Record the date the protocol deviation occurred. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.